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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/559,401	04/26/2000	Hiroyuki Yuyama	2000 0523A	1206

7590 01/30/2003

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EXAMINER

GILLIGAN, CHRISTOPHER L

ART UNIT PAPER NUMBER

3626

DATE MAILED: 01/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/559,401

Applicant(s)

YUYAMA ET AL.

Examiner

Luke Gilligan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

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Claims 1-9 have been examined.

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
2. Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Claim 7 recites the limitation "the pH-values data" in line 4. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in–

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or  
(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

5. Claims 1, 3, 5-7, and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by Engleson et al., U.S. Patent No. 5,781,442.

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6. As per claim 1, Engleson et al. teach an apparatus for supporting injection mixing work comprising: a memory for storing data for supporting injection mixing work, the memory having a patient predictability data file for storing patient predictability data including at least patient predictable information (see column 5, line 66 – column 6, line 2), an injection prescription data file for storing injection prescription data corresponding to the patient predictability data (see column 6, lines 2-6), and a combination related data file for storing combination related data corresponding to each injection of the injection prescription data (see column 6, lines 54-58); a display for displaying the data stored in the memory (see column 2, lines 28-31); and a controller for controlling the display to display the patient predictability data stored in the patient predictability data file correspondingly to both the injection prescription data corresponding to the patient predictability data and the combination related data of each injection included in the injection prescription data (see column 8, line 66 – column 9, line 12 and Figure 9).

7. As per claim 3, Engleson et al. teach the apparatus of claim 1 as described above, wherein the combination related data file of the memory stores differentiation data for differentiating transfusion and solely administrated medicament, and wherein the controller classifies the injection contained in the injection prescription data for a patient into transfusion or solely administrated medicament in accordance with the differentiation data and displays it on the display (see column 9, lines 40-52).

8. As per claim 5, Engleson et al. teach the apparatus of claim 1 as described above, wherein the combination related data file of the memory stores attention information data related to each injection, and wherein the controller displays an attention information in the attention information data on the display correspondingly to each injection of the injection prescription data (see column 9, lines 63-67).

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9. As per claim 6, Engleson et al. teach the apparatus of claim 1 as described above, further comprising a reader for reading an identification code for identifying each injection, wherein the controller displays progress situation of mixing work on the display in accordance with the identification code read by the reader when conducting the mixing work of the injection (see column 7, lines 44-52).

10. As per claim 7, Engleson et al. teach the apparatus of claim 6 as described above, wherein the controller decides whether the injection is proper or not in accordance with the identification code of the injection read by the reader and if improper, displays it on the display (see column 7, lines 52-59).

11. As per claim 9, Engleson et al. teach the apparatus of claim 1 as described above, further comprising a reader for reading a prescription identification code for identifying each injection prescription data, wherein the controller reads the corresponding injection prescription data in accordance with the prescription identification code and displays it on the display (see column 7, lines 44-52).

***Claim Rejections - 35 USC § 103***

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Engleson et al., U.S. Patent No. 5,781,442 in view of Merki et al., U.S. Patent No. 5,002,055.

14. As per claim 2, Engleson et al. teach the apparatus of claim 1 as described above. Engleson et al. do not explicitly teach storing pH-values data for each injection and determining

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the mixing order of the injections in accordance with the pH-values data. Merki et al. teach storing pH-values data for injections, and wherein a controller decides a mixing order of the injections in accordance with the pH-values (see column 3, lines 52-63). It would have been obvious to one of ordinary skill in the art of injection prescription management at the time of the invention to incorporate this feature into the system of Engleson et al. One of ordinary skill in the art would have been motivated to make such a combination for the purpose of enhancing patient safety by regulating pH-values.

15. Claims 4 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Engleson et al., U.S. Patent No. 5,781,442 in view of Mayaud, U.S. Patent No. 5,845,255.

16. As per claim 4, Engleson et al. teach the apparatus of claim 1 as described above. Engleson et al. do not explicitly teach storing incompatibility data for showing whether or not two kinds of injections are incompatible and displaying the incompatibility on the display. Mayaud teaches storing incompatibility data showing whether or not a combination of two kinds of injections is incompatible, and wherein the controller decides whether or not a combination of two kinds of injections contained in injection prescription data for a patient is incompatible in accordance with the incompatibility data and displays it on a display (see column 31, lines 19-24). It would have been obvious to one of ordinary skill in the art of prescription management at the time of the invention to incorporate the incompatibility detection feature of Mayaud into the invention of Engleson et al. One of ordinary skill in the art would have been motivated to make such a combination for the purpose of enhancing patient safety when prescribing injections of a plurality of different drugs.

17. As per claim 8, Engleson et al. in view of Mayaud teach the system of claim 4 as describe above. Engleson et al. do not explicitly teach inputting new incompatibility data and storing it in the combination related data of the memory. Mayaud teach inputting new

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incompatibility data in addition to stored incompatibility data and storing it in a combination related data in memory (see column 31, lines 33-39). It would have been obvious to one of ordinary skill in the art at the time of the invention to make add this feature to the system of Engleson et al. for the reasons given above with respect to claim 4.

### **Conclusion**

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- Coutre et al. teach an infusion pump management system to carry out a desired course of infusion therapy.

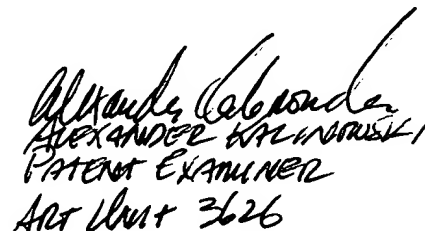
19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Luke Gilligan whose telephone number is (703) 308-6104. The examiner can normally be reached on Monday-Friday 8am-5:30pm.

20. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (703) 305-9588. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7687 for regular communications and (703) 305-7687 for After Final communications.

21. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1113.

  
CLG

January 27, 2003

  
ALEXANDER KALINSKI  
PATENT EXAMINER  
Art Unit 3626